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104TH CONGRESS
2D SESSION

H. R. 4257

To amend the Public Health Service Act to provide a one-stop shopping information service for individuals with serious or life-threatening diseases.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 27, 1996

Mr. LAZIO of New York introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Public Health Service Act to provide a one-stop shopping information service for individuals with serious or life-threatening diseases.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. INFORMATION PROGRAM ON DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES.

Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (i), the following new subsection:

''(j)(1) The Secretary, acting through the Director of the National Institutes of Health, shall establish, maintain, and operate a program with respect to information on research, treatment, detection, and prevention activities relating to serious or life-threatening diseases and conditions. The program shall, with respect to the agencies of the Department of Health and Human Services, be integrated and coordinated, and, to the extent practicable, coordinated with other data banks containing similar information.

''(2)(A) After consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention, the Secretary shall, in carrying out paragraph (1), establish a data bank of information on clinical trials and treatments (including drugs, biologicals, devices, and other therapies) with respect to serious or life-threatening diseases and conditions.

''(B) In carrying out subparagraph (A), the Secretary shall collect, catalog, store and disseminate the information described in such subparagraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threaten-

ing diseases and conditions, to other members of the public, to health care providers, and to researchers.

''(3) The Data Bank shall include the following:

''(A) A registry of clinical trials (whether Federally or privately funded) of experimental treatments (including drugs, biologicals, devices, and other therapies) for serious or life-threatening diseases and conditions under regulations promulgated pursuant to sections 505 and 515 of the Federal Food, Drug, and Cosmetic Act that provides a description of the purpose of each experimental drug protocol, either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall include eligibility criteria, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information must be forwarded to the Data Bank by the sponsor of the trial not later than 21 days after approval by the Food and Drug Administration.

''(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

''(i) under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations;

''(ii) as a Group C cancer drug; or

''(iii) under an exemption for devices for investigational use pursuant to part 812 of title 21, Code of Federal Regulations.

The Data Bank shall also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatment.

''(4) For the purpose of carrying out this subsection there are authorized to be appropriated such sums as may be necessary.''.

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